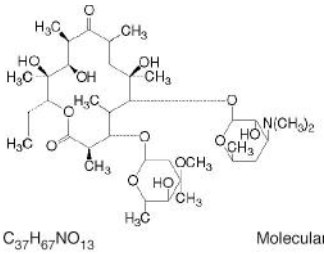
ERYTHROMYCIN - erythromycin gel
E. FOUGERA & CO., A division of Nycomed US Inc.

Rx only
FOR DERMATOLOGIC USE ONLY NOT FOR OPHTHALMIC USE

DESCRIPTION:

Erythromycin Topical Gel contains erythromycin for topical dermatologic use. Erythromycin is a macrolide antibiotic produced from a strain of *Saccaropolyspora erythraea* (formerly *Streptomyces erythreus*). It is a base and readily forms salts with acids. Chemically, erythromycin is: (3*R**,4*S**,5*S**,6*R**,7*R**,9*R**,11*R**,12*R**, 13*S**,14*R**)-4-[(2,6-Dideoxy-3-*C*-methyl-3-*O*-methyl-α-L-*ribo*-hexopyranosyl)-oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-*xylo*-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione. It has the following structural formula:



Molecular Formula: $C_{37}H_{67}NO_{13}$ Molecular Weight: 733.94

Erythromycin is a white or slightly yellow crystalline powder that is very soluble in water, freely soluble in alcohols, acetone, chloroform, acetonitrile, ethyl acetate, and moderately soluble in ether, ethylene dichloride and amyl acetate.
Each gram of Erythromycin Topical Gel 2% contains: Active Ingredient: erythromycin USP, 2% (20 mg/g). Inactive Ingredients: alcohol USP, 92% and hydroxypropyl cellulose NF.

CLINICAL PHARMACOLOGY:

The exact mechanism by which erythromycin reduces lesions of acne vulgaris is not fully known; however, the effect appears to be due in part to the antibacterial activity of the drug.
Microbiology: Erythromycin acts by inhibition of protein synthesis in susceptible organisms by reversibly binding to 50 S ribosomal subunits, thereby inhibiting translocation of aminoacyl transfer-RNA and inhibiting polypeptide synthesis. Antagonism has been demonstrated *in vitro* between erythromycin, lincomycin, chloramphenicol, and clindamycin.

INDICATIONS AND USAGE:

Erythromycin Topical Gel is indicated for the topical treatment of acne vulgaris.

CONTRAINDICATIONS:

Erythromycin Topical Gel is contraindicated in those individuals who have shown hypersensitivity to any of its components.

WARNINGS:

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including erythromycin, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.
Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of ``antibiotic-associated colitis##.
After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation and treatment with an antibacterial drug clinically effective against *C. difficile* colitis.

PRECAUTIONS:

General: For topical use only; not for ophthalmic use. Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating or abrasive agents.
The use of antibiotic agents may be associated with the overgrowth of antibiotic-resistant organisms. If this occurs, discontinue use and take appropriate measures. Avoid contact with eyes and all mucous membranes.
Information for Patients: Patients using Erythromycin Topical Gel should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes, nose, mouth, and all mucous membranes.

2. This medication should not be used for any disorder other than that for which it was prescribed.

3. Patients should not use any other topical acne medication unless otherwise directed by their physician.

4. Patients should report to their physician any signs of local adverse reactions.

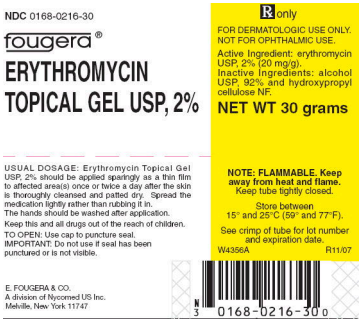
Carcinogenesis, Mutagenesis, Impairment of Fertility: No animal studies have been performed to evaluate the carcinogenic and mutagenic potential or effects on fertility of topical erythromycin. However, long-term (2 years) oral studies in rats with erythromycin ethylsuccinate and erythromycin base did not provide evidence of tumorigenicity. There was no apparent effect on male or female fertility in rats fed erythromycin (base) at levels up to 0.25% of diet.
Pregnancy: Teratogenic effects–*Pregnancy Category B.* There was no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base (up to 0.25% of diet) prior to and during mating, during gestation and through weaning of two successive litters.
There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used in pregnancy only if clearly needed. Erythromycin has been reported to cross the placental barrier in humans, but fetal plasma levels are generally low.
Nursing Mothers: It is not known whether erythromycin is excreted in human milk after topical application. However, erythromycin is excreted in human milk following oral and parenteral erythromycin administration. Therefore, caution should be exercised when erythromycin is administered to a nursing woman.
Pediatric Use: Safety and effectiveness of this product in pediatric patients have not been established.

ADVERSE REACTIONS:
The most common adverse reaction reported with Erythromycin Topical Gel was burning.
The following local adverse reactions have been reported occasionally: peeling, dryness, itching, erythema, and oiliness. Irritation of the eyes and tenderness of the skin have also been reported with topical use of erythromycin. Generalized urticarial reactions possibly related to the use of erythromycin, which required systemic steroid therapy have been reported.

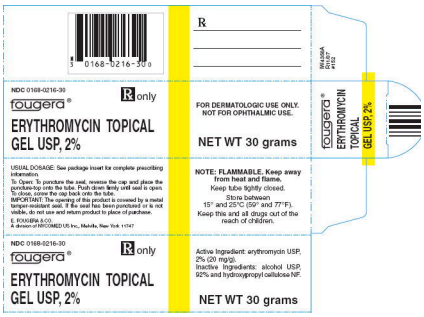
DOSAGE AND ADMINISTRATION:
Apply sparingly as a thin film to affected area(s) once or twice a day after the skin is thoroughly cleansed and patted dry. If there has been no improvement after 6 to 8 weeks, or if the condition becomes worse, treatment should be discontinued, and the physician should be reconsulted. Spread the medication lightly rather than rubbing it In. The hands should be washed after application. There are no data directly comparing the safety and efficacy of b.i.d. versus q.d. dosing.

HOW SUPPLIED:
Erythromycin Topical Gel USP, 2% is supplied as follows:
30 gram tubes - NDC 0168-0216-30 60 gram tubes - NDC 0168-0216-60
NOTE: FLAMMABLE. Keep away from heat and flame.
Store and dispense in original container.
Keep tube tightly closed.
Store between 15° and 25°C (59° and 77°F).
E. FOUGERA & CO.
A division of Nycomed US Inc.
Melville, New York 11747
I2216B
#153
R11/07

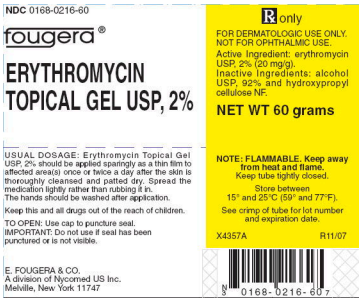
PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 30 G CONTAINER
NDC 0168-0216-30
FOUGERA®
ERYTHROMYCIN
TOPICAL GEL USP, 2%
Rx only
FOR DERMATOLOGIC USE ONLY.
NOT FOR OPHTHALMIC USE.
Active Ingredient: erythromycin
USP, 20 mg/g
Inactive Ingredients: alcohol
USP 92% and hydroxypropyl
cellulose NF.
NET WT 30 grams



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 30 G CARTON
NDC 0168-0216-30 **R**x only
FOUGERA®
ERYTHROMYCIN TOPICAL
GEL USP, 2%
FOR DERMATOLOGIC USE ONLY.
NOT FOR OPHTHALMIC USE.
NET WT 30 grams



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60 G CONTAINER
NDC 0168-0216-60
FOUGERA®
ERYTHROMYCIN
TOPICAL GEL USP, 2%
Rx only
FOR DERMATOLOGIC USE ONLY.
NOT FOR OPHTHALMIC USE.
Active Ingredient: erythromycin
USP, 2% (20 mg/g).
Inactive Ingredients: alcohol
USP 92% and hydroxypropyl
cellulose NF.
NET WT 60 grams



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60 G CARTON
NDC 0168-0216-60 **R**x only
FOUGERA®
ERYTHROMYCIN TOPICAL

GEL USP, 2%
FOR DERMATOLOGIC USE ONLY.
NOT FOR OPHTHALMIC USE.
NET WT 60 grams